

REMARKS

Claims 1-7, 9, and 14-24 are presented for the Examiner's review and consideration. Claims 1 and 9 have been amended herein. Claim 8 has been cancelled. Claims 10-13 were cancelled in a previous Response. Applicants believe that the claim amendments and accompanying remarks herein serve to clarify the present invention and are independent of patentability. No new matter has been added.

Amendments to the Claims

No new matter has been added by the amendments to claim 1 made herein. This claim has been amended to clarify the recited method and to emphasize that the purpose for addition of a hygroscopic material, *i.e.* the salt-based granular material, is to accelerate the rate of absorption of the pad. Additionally, this claim has been amended to indicate the type of material that should be added to the pad. *See* paragraphs [0027] and [0028] of the published application, cancelled claim 8, and the attached second Declaration of Dr. Yariv Siman-Tov for support of these amendments. No new matter has been added by the amendment to claim 9 made herein. This claim has been amended for dependency on claim 1 in view of the cancellation of claim 8.

Rejections under 35 U.S.C. §103(a)

Claims 1-6, 8, 9, 14-18, and 21-24 were rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Malodobry (U.S. patent application publication 2004/0111107; hereinafter "Malodobry") in view of Ring et al. (U.S. Patent 4,588,400; hereinafter "Ring"). Claims 7, 19, and 20 were rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Malodobry in view of Ring et al. and further in view of Garitano et al. (U.S. patent application publication 2004/0158296; hereinafter "Garitano"). For reasons set forth below, Applicants respectfully submit that both of these rejections should be withdrawn.

It is noted that the references are described separately only to clarify what each reference teaches and not to argue the references separately.

Malodobry

Malodobry teaches a method for scarless removal of tattoos from human or animal skin. The method includes passing one or more needles through the skin surface in a manner essentially perpendicular thereto. The needle enters agglomerates of color pigments present in the skin and mechanically destroys them. The smaller fragments of the agglomerates are eliminated by the natural healing process of the skin. The method may also include application of skin irritants to skin surface and/or introduction into the agglomerates before, during, or after the mechanical destruction. The skin irritants provide fillers in the cells to delay wound healing to allow for maximum fragment elimination. *See* abstract, paragraphs [0039]-[0043], paragraphs [0050]-[0052], and claim 1 of the published application.

Ring

Ring discloses a liquid-carrying material for medical applications. One embodiment is a sterile pad comprising a pellicle of microbially-produced cellulose wetted with a physiologically-acceptable liquid useful as a wound dressing and/or treatment pad. *See* column 1, lines 6-12. Cellulose obtained from a culture of *Acetobacter xylinum* is exemplified in the application. *See* column 3, lines 39-59.

Garitano

Garitano discloses a device and methods for needleless administration of permanent makeup and tattoos. In particular, the device relates to hypodermic injectors for use in delivering pigment or other substances to targeted layers of the skin. *See* paragraph [0016] of the published application. Material is delivered by accelerating compressed air. *See* paragraphs [0033] and [0034] of the published application. Garitano also contemplates removal of pigment using the described device, including methods involving suction or drainage of solution from the skin. *See* paragraph [0023] of the published application.

Instant Invention

The instant invention, as claimed herein, is a method for the removal of pigments from a pigmented section of skin. The method involves puncturing the skin in the pigmented area with at least one needle or other skin-puncturing device to liberate the pigments and cellular fluids from cells containing the pigments. The punctured skin is then bandaged using a pad adapted to absorb the pigments and cellular fluids. Prior to bandaging, the pad is treated with a material, such as a salt-based granular, that accelerates the migration of pigments toward the outer layer of where they are removed. *See* abstract and paragraphs [0014] and [0027]-[0032] of the published application. The pad is preferably removed prior to complete saturation and/or before the material in the pad causes skin damage. *See* paragraph [0029] of the published application. The method can also include application of antiseptic and/or antibiotics to the punctured skin. *See* paragraphs [0016] and [0031] of the published application. Additionally, the skin-puncturing device has a suction means for suction of the pigments during puncturing of the skin. *See* paragraphs [0019] and [0033] of the published application.

Argument

The Examiner asserts that it would have been obvious to a person of ordinary skill in the art at the time that the invention was made to modify Malodobry's removal method with Ring's absorbent pad. One of ordinary skill would be able to modify the pad to absorb debris and material from the wound as necessary because it would simply involve adding or subtracting absorbent material as necessary. Therefore the Examiner concludes that it would also be obvious to a person of ordinary skill in the art to modify Ring's pad to include the desired amount of absorption.

Applicants respectfully disagree. As explained in the previous Response, the action of the pad as described in the Office Action is substantially different from the action of the pad used in the claimed method. The salt-based granular paste added to the pad used in the claimed method accelerates the process of migration of the fluid to the surface so that much greater quantities of

pigments and cellular fluids are absorbed into the pad before the holes created by the needle naturally close than are absorbed into a pad that does not contain the granular paste. This is a unique feature that distinguishes the pad of the invention from prior art pads and specifically from the pad described by Ring.

Claim 1 of the instant invention now recites, *inter alia*, that the pad adapted to absorb the pigments and cellular fluids contains one or more materials capable of accelerating the process of migration of the pigments toward the outer layer of the skin and wherein one of these materials is a salt-based granular paste (Claim 1b).

As pointed out by the Examiner, adaptation of pads for absorption of debris is common to most prior art pads used for dressing wounds and the like. However, the pad of the instant invention includes a hygroscopic material that accelerates the rate of absorption of the pad beyond the natural process, and contrary to the impression of the Examiner, is not obvious.

As described in the previous Response, the inventors analyzed the processes involved in the method of eradication tattoos by repeatedly pricking the skin in the area of the tattoo in order to destroy the cells releasing the pigments enclosed therein. They recognized that the reason that prior art methods required repeated treatment sessions to remove the tattoo was that the holes made by the needles closed in a matter of minutes trapping the pigments inside the upper layers of the skin. The instant inventors then realized that the key to successfully removing a tattoo with a single treatment was to find a way to increase the rate at which the pigment fragments released from the cells migrated to the surface. The solution to the problem provided by the instant invention does not rely solely on the natural absorption of the pad, which results from the structure of the fibers of which the pad is comprised, to absorb fluid, but to add to the pad a hygroscopic material that would draw the pigment fragments rapidly to the surface of the skin.

In evidence of this point, a second Declaration by Dr. Yariv Siman-Tov is provided herewith. This Declaration describes an experimental test that was carried out to compare the amount of liquid absorbed and rate of absorption by an ordinary medical pad to the rate and amount absorbed by an identical pad containing a hygroscopic material. The result of this test clearly show that the addition of the salt-based granular paste to the pad dramatically increased

the amount of absorbed liquid in a given time period. These results clearly confirm the efficacy of the addition of the granular paste to the pad. *See* Absorption Comparison graph provided in the Declaration.

For clarification, Applicants do not claim that the pad and the material added to it prevent the natural processes from taking place. On the contrary, the closing of the holes made by the needles takes place as normal. As noted above, the difference between the invention and the prior art is that salt-based granular paste added to the pad (used in the claimed method) accelerates the process of migration of the fluid to the surface so that much greater quantities of pigments and cellular fluids are absorbed into the pad before the holes created by the needle naturally close than are absorbed into a pad (prior art) that does not contain the granular paste.

The pad of Ring is comprised of microbially-produced cellulose that is grown from a culture medium. The relatively long length and small diameter of the cellulose fibrils as well as the structure of the pellicle formed from their growth results in a dressing having a much greater liquid-carrying capacity than that of conventional bandages. Expelling a large fraction of the liquid culture medium from the pellicle results in a wound dressing that has the capability of absorbing about 70% of its original liquid content. The pad (pellicle) of Ring is able to absorb relatively large quantities of liquid as a result of the unique structure of the cellulose fibers of which it is made. Ring does not teach or suggest addition of any material to the pad in order to increase the quantity of fluid absorbed and/or the speed with which fluid is absorbed by the pad. As such, Ring does not teach addition of a hygroscopic material in general or salt-based granular paste in particular to his pad (pellicle). Thus, Ring does not teach or suggest the characterizing feature of claim 1 as amended herein.

Malodobry and Garitano do not remedy the deficiencies of Ring. Neither Malodobry nor Garitano teach or suggest use of an ordinary pad, let alone a pad containing materials capable of accelerating the process of migration of the pigments toward the outer layer of the skin. Thus, even if one of ordinary skill in the art were to combine the teachings of Malodobry, Ring, and Garitano, one would not arrive at the instant invention. None of the prior art methods are capable of completely removing tattoos with a single treatment and all require repeated treatment of the

same area in order to merely approach complete eradication of a tattoo. One of skill in the art would not be motivated or inspired to add any material to a pad or bandage because nothing in the art teaches or suggests any material added to a pad would increase absorption of pigments in the removal of tattoos or that such addition to a pad would enable tattoo removal with one treatment.

Accordingly, independent claim 1 would not be obvious to one of ordinary skill in the art reading Malodobry in view of Ring under 35 U.S.C. § 103(a). As claims 2-7, 9, and 14-24 depend from claim 1, these dependent claims necessarily include all of the elements of base claim 1. Thus, Applicants respectfully submit that the dependent claims are allowable over the cited references for at least the same reasons.

In light of all the foregoing, Applicants respectfully request reconsideration and withdrawal of the rejection of claims 1-6, 9, 14-18, and 21-24 (Malodobry in view of Ring) and the rejection of claims 7, 9, and 20 (Malodobry in view of Ring and in further view of Garitano) under 35 U.S.C. § 103(a)

Submission of Signed Declarations

Applicants would like to thank the Examiner for his careful consideration of the previous Response and helpful analysis of issues that remained unresolved. In response, Applicants submit the following herein:

- a. The Declaration of Dr. Yariv Siman-Tov has been amended to supply the information that the Examiner found lacking in the original Declaration. A copy of the revised version is attached.
- b. A second Declaration of Dr. Yariv Siman-Tov relating to an experimental test that was carried out to compare the amount of liquid absorbed and rate of absorption by an ordinary medical pad to the rate and amount absorbed by an identical pad containing a hygroscopic material as described in the first Declaration. The results of this test clearly show that the addition of the salt-

based granular paste to the pad dramatically increased the amount of absorbed liquid in a given time period. The results of this test clearly confirm the efficacy of the addition of the granular paste to the pad.

If there are any formal problems with either of these Declarations or if additional information is required, Applicants respectfully request that the Examiner contact the undersigned to remedy the problems without unduly delaying prosecution.

Conclusion

In light of the foregoing amendments and remarks, this application is now in condition for allowance and early passage of this case to issue is respectfully requested. If any questions remain regarding this amendment or the application in general, a telephone call to the undersigned would be appreciated since this should expedite the prosecution of the application for all concerned.

The fee for a two month extension of time pursuant to Section 1.17(a)(2) in the amount of \$230 is believed to be due and is being paid via credit card. No other fees are believed to be due at this time. However, please charge any other required fee (or credit any overpayments of fees) to the Deposit Account of the undersigned, Account No. 500601 (Docket No. 7640-X05-045).

Respectfully submitted,

Katharine F. Davis Wong

Katharine F. Davis Wong, Reg. #51,598 for
Paul Bianco, Reg. #43,500
Martin Fleit, Reg. #16,900

Customer Number: 27317

FLEIT GIBBONS GUTMAN BONGINI & BIANCO
21355 East Dixie Highway, Suite 115
Miami, Florida 33180
Tel: 305-830-2600; Fax: 305-830-2605
e-mail: pbianco@fggbb.com